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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,601	02/12/2004	Guo-Liang Yu	PF160D3	3691

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EXAMINER	
JOYCE, CATHERINE	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,601	YU ET AL.	
	Examiner	Art Unit	
	Catherine M. Joyce	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10 and 27-47* is/are pending in the application.

4a) Of the above claim(s) *10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Claims 1-9 and 11-26 have been canceled.

2. Claims 10 and 27-47 are pending, and claim 10 is withdrawn from consideration as being drawn to a non-elected invention

3. Claims 27-47 are under examination.

4. Applicant's election with traverse of the invention of Group 3, and the species defined by the polypeptide of SEQ ID NO:16, in the reply filed on October 23, 2006 is acknowledged. The traversal is on the ground(s) that searching all of Groups 1-7 together would not pose a search burden. This argument is not found persuasive because, while the searches for the different groups would be overlapping, they would not be coextensive and thus would pose an undue search burden. The requirement for restriction is deemed proper and is made FINAL.

Specification

5. The specification on page 1 should be amended to reflect the status of the parent application serial number 09/988292.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43 is indefinite because claim 43 recites the phrase a "chimeric antibody". The exact meaning of the word chimeric is not known. The term chimeric is generic to a

class of antibodies that are products of genetic shuffling of antibody domains and other active proteins. The term encompasses antibodies fused to non-immunoglobulin proteins as well as antibodies wherein any domain of the antibody is substituted by corresponding regions or residues of human antibodies, including but not limited to CDR grafted antibodies.

Amendment of the claim to clarify exactly what is intended by the claim is required.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 27-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims, as drawn to the elected invention, are as follows:

An isolated antibody or fragment thereof that specifically binds to a protein selected from the group consisting of:

(I) an isolated antibody or fragment thereof that specifically binds to a protein selected from the group consisting of:

(a) a protein whose amino acid sequence is at least 90% to the deduced amino acid sequence as set forth in Figure 9 (SEQ ID NO:16);

(b) a protein comprising the amino acid sequence as set forth in Figure 9 (SEQ ID NO:16);

(c) a protein whose an amino acid sequence is at least about 90% to the amino acid sequence consisting of amino acids 2 to 323 as set forth in Figure 9 (SEQ ID NO:16);

(d) a protein comprising an amino acid sequence consisting of amino acids 2 to 323 as set forth in Figure 9 (SEQ ID NO:16);

(e) a protein whose amino acid sequence consists of at least 30 contiguous amino acids of SEQ ID NO:16;

(f) a protein whose amino acid sequence consists of at least 50 contiguous amino acids of SEQ ID NO:16; and

(g) a protein encoded by the human cDNA contained in ATCC Deposit No. 97102;

(II) an isolated antibody or fragment thereof obtained from an animal that has been immunized with a protein selected from the group consisting of:

(h) a protein whose an amino acid sequence is at least 90% to the deduced amino acid sequence as set forth in Figure 9 (SEQ ID NO:16);

(i) a protein comprising the amino acid sequence as set forth in Figure 9 (SEQ ID NO:16);

(j) a protein who amino acid sequence is at least 90% to the amino acid sequence consisting of amino acids 2 to 323 as set forth in Figure 9 (SEQ ID NO:16);

(k) a protein comprising the amino acid sequence consisting of amino acids 2 to 323 as set forth in Figure 9 (SEQ ID NO:16);

(l) a protein whose amino acid sequence consists of at least 30 contiguous amino acids of SEQ ID NO:16;

(m) a protein whose amino acid sequence consists of at least 50 contiguous amino acids of SEQ ID NO:16; and

(n) a protein encoded by the human cDNA contained in ATCC Deposit No. 97102 (claim 27),

the antibody or fragment thereof of claim 27 that specifically binds protein (a) (claim 28),

the antibody or fragment thereof of claim 27 that specifically binds protein (a) (claim 28),

the antibody or fragment thereof of claim 27 that specifically binds protein (b) (claim 29),

the antibody or fragment thereof of claim 27 that specifically binds protein (c) (claim 30),

the antibody or fragment thereof of claim 27 that specifically binds protein (d) (claim 31),

the antibody or fragment thereof of claim 27 that specifically binds protein (e) (claim 32),

the antibody or fragment thereof of claim 27 that specifically binds protein (f) (claim 33),

the antibody or fragment thereof of claim 27 that specifically binds protein (g) (claim 34),

the antibody or fragment thereof of claim 27 that specifically binds protein (h) (claim 35),

the antibody or fragment thereof of claim 27 that specifically binds protein (i) (claim 36),

the antibody or fragment thereof of claim 27 that specifically binds protein (j) (claim 37),

the antibody or fragment thereof of claim 27 that specifically binds protein (k) (claim 38),

the antibody or fragment thereof of claim 27 that specifically binds protein (l) (claim 39),

the antibody or fragment thereof of claim 27 that specifically binds protein (m) (claim 40),

the antibody or fragment thereof of claim 27 that specifically binds protein (n) (claim 41),

the antibody or fragment thereof of claim 27 wherein said protein bound by said antibody or fragment thereof is glycosylated (claim 42),

the antibody or fragment thereof of claim 27 wherein said antibody or fragment thereof is selected from the group consisting of :

(a) a human antibody or fragment thereof;
(b) a chimeric antibody or fragment thereof;
(c) a humanized antibody or fragment thereof;
(d) single chain antibody;
(e) a Fab fragment (claim 43),

the antibody or fragment thereof of claim 27 wherein said antibody or fragment thereof is monoclonal (claim 44);

the antibody or fragment thereof of claim 27 wherein said antibody or fragment thereof is polyclonal (claim 45);

the antibody or fragment thereof of claim 27 which is labeled (claim 46),

the antibody or fragment thereof of claim 27 wherein said antibody or fragment thereof specifically binds to said protein in Western blot or ELISA (claim 47).

The specification teaches that a number of colon specific gene products were identified wherein specific cDNAs corresponding to the different genes are provided in SEQ ID NOs:1, 3, 5, 7, 9, 11, 13, 15, 17, 19, and 21, and the respective encoded polypeptides are provided in SEQ ID NOs:2, 4, 6, 8, 10, 12, 14, 16, 18, 20, and 22 (paragraphs 0023-0035). The specification further provides that the polynucleotide of

SEQ ID NO:15 and the polypeptide of SEQ ID NO:16 relate to the CSG10 colon specific gene (paragraph 0031). The specification further provides that antibodies to colon specific gene products may be used (i) to diagnose a disorder of the colon, for example colon cancer (paragraph 0076), (ii) for in vivo imaging wherein antibodies that interact with the colon, for example colon cancer cells, and fluoresce upon contact such that imaging and visibility of the colon are enhanced to allow a determination of the diseased and non-diseased state of the colon (paragraph 0153), and (iii) to isolate the corresponding peptides from tissues expressing the polypeptides (paragraph 0149). The specification further provides that the colon specific genes CSG7 and CSG10 have been found to have a reduced expression in colon cancer cells as compared to that in normal cells (paragraph 0135).

The teaching of the specification cannot be extrapolated to enable the claims because the teaching of the specification that an mRNA encoding the CSG10 polypeptide shows reduced expression in colon cancer cells is not sufficient to establish that a CSG10 polypeptide shows reduced expression in colon cancer cells. The prior art is replete with examples in which expression levels of mRNA are not correlated with expression levels of the encoded protein. For example, McClean and Hill (Eur J of Cancer, 1993, vol. 29A, pp.2243-2248) teach that p-glycoprotein can be overexpressed in CHO cells following exposure to radiation, without any concomitant overexpression of the p-glycoprotein mRNA. Fu et al (EMBO Journal, 1996, Vol. 15, pp. 4392-4401) teach that levels of p53 protein expression do not correlate with levels of p53 mRNA levels in blast cells taken from patients with acute myelogenous leukemia, said patients being without mutations in the p53 gene. Brennan et al (Journal of Autoimmunity, 1989, vol. 2 suppl., pp. 177-186) teaches that high levels of the mRNA for TNF-alpha were produced in synovial cells, but that levels of the TNF alpha protein were undetectable, and Zimmer (Cell Motility and the Cytoskeleton, 1991, vol. 20, pp. 325-337) teaches that there is no correlation between the mRNA level of calcium-modulated protein S100 alpha and levels of S100 alpha protein. Eriksson et al. (Diabetologia, 1992, vol. 35, pp. 143-147) teaches that no correlation is observed between levels of mRNA transcripts

encoding the insulin-responsive glucose transporter and expression levels of the protein. Further, Jang et al (Clinical and Experimental Metastasis, 1997, vol. 15, pp. 469-483) teach that further studies are necessary to determine if changes in protein levels track with changes in mRNA levels for metastasis associated genes in murine tumor cells, thus providing further evidence that one of skill in the art cannot anticipate that the level of a specific mRNA expressed by a cell will be paralleled at the protein level due to complex homeostatic factors controlling translation and post-translational modification. Greenbaum *et al.* (*Genome Biology*, 2003, Vol. 4, Issue 9, pages 117.1-117.8) also addresses this issue wherein the authors caution against assuming that mRNA levels are generally correlative of protein levels. The reference teaches (page 117.3, 2nd column) that primarily because of a limited ability to measure protein abundances, researchers have tried to find correlations between mRNA and the limited protein expression data, in the hope that they could determine protein abundance levels from the more copious and technically easier mRNA experiments. To date, however, there have been only a handful of efforts to find correlations between mRNA and protein expression levels, most notably in human cancers and yeast cells. And, for the most part, they have reported only minimal and/or limited correlations. The reference further teaches (page 117.4, 2nd column) that there are presumably at least three reasons for the poor correlations generally reported in the literature between the level of mRNA and the level of protein, and these may not be mutually exclusive. First, there are many complicated and varied post-transcriptional mechanisms involved in turning mRNA into protein that are not yet sufficiently well defined to be able to compute protein concentrations from mRNA; second, proteins may differ substantially in their *in vivo* half lives; and/or third, there is a significant amount of error and noise in both protein and mRNA experiments that limit our ability to get a clear picture. The reference further notes (page 117.6, page 2nd column) that to be fully able to understand the relationship between mRNA and protein abundances, the dynamic processes involved in protein synthesis and degradation have to be better understood.

Thus, observation of expression of mRNA does not appear to be predictive of concomitant expression of protein. Thus, given the state of the art as reviewed above, data on the expression of mRNA encoding the CSG10 polypeptide in colon cancer cells does not allow one of skill in the art to predict that the CSG10 polypeptide will show a reduction in expression in colon cancer cells to the extent required to be useful for the diagnosis of colon cancer. In addition, since the CSG10 gene purportedly shows a reduced expression in colon cancer cells as compared to normal cancer cells, it is not clear how imaging methods that detect the CSG10 would be useful for imaging colon cancer cells as described in the specification. Thus, in absence of guidance in the specification on these issues, use of the antibodies of the invention would require undue experimentation.

10. Further, if the above stated rejection of claims 27, 28, 30, 35 and 37 under 35 U.S.C. 112, first paragraph, is overcome, claims 27, 28, 30, 35 and 37 would still be rejected under 35 U.S.C. 112, first paragraph, the specification, while being enabling for an isolated antibody or fragment thereof that specifically binds to a protein comprising the amino acid sequence of SEQ ID NO:16, does not reasonably provide enablement for an isolated antibody or fragment thereof that specifically binds to a protein whose amino acid sequence is at least 90% to the amino acid sequence of SEQ ID NO:16.

The claims are as set forth above.

The specification teaches as set forth above.

The teaching of the specification does not enable the scope of the claims because the claims are drawn to antibodies that do not require specific binding to SEQ ID NO:16, thus the claims are claiming an antibody that binds to an unknown antigen. The following teaching of the court as set out in Noelle also clearly applies to the instant claimed invention. The court found that "Noelle did not provide sufficient support for the claims to the human CD40CR antibody in his '480 application because Noelle failed to disclose the structural elements of human CD40CR antibody or antigen in his earlier

'799 application. Noelle argues that because antibodies are defined by their binding affinity to antigens, not their physical structure, he sufficiently described human CD40CR antibody by stating that it binds to human CD40CR antigen. Noelle cites Enzo Biochem II for this proposition. This argument fails, however, because Noelle did not sufficiently describe the human CD40CR antigen at the time of the filing of the '799 patent application. In fact, Noelle only described the mouse antigen when he claimed the mouse, human, and genus forms of CD40CR antibodies by citing to the ATCC number of the hybridoma secreting the mouse CD40CR antibody. If Noelle had sufficiently described the human form of CD40CR antigen, he could have claimed its antibody by simply stating its binding affinity for the "fully characterized" antigen. Noelle did not describe human CD40CR antigen. Therefore, Noelle attempted to define an unknown by its binding affinity to another unknown. As a result, Noelle's claims to human forms of CD40CR antibody found in his '480 application cannot gain the benefit of the earlier filing date of his '799 patent application. Thus, one of skill in the art could not predict a use for the broadly claimed antibodies because there is no requirement that the antibodies bind to the polypeptide of SEQ ID NO:16, and thus one of skill in the art could not predict how to use the broadly claimed antibodies that bind to unknown antigens.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 27-41, 45, 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oda et al. (1993, J. of Biol. Chem. 268(8):5929-5939).

The claims are drawn to the following:

An isolated antibody or fragment thereof that specifically binds to a protein selected from the group consisting of:

(I) an isolated antibody or fragment thereof that specifically binds to a protein selected from the group consisting of:

(a) a protein whose amino acid sequence is at least 90% to the deduced amino acid sequence as set forth in Figure 9 (SEQ ID NO:16);

(b) a protein comprising the amino acid sequence as set forth in Figure 9 (SEQ ID NO:16);

(c) a protein whose an amino acid sequence is at least about 90% to the amino acid sequence consisting of amino acids 2 to 323 as set forth in Figure 9 (SEQ ID NO:16);

(d) a protein comprising an amino acid sequence consisting of amino acids 2 to 323 as set forth in Figure 9 (SEQ ID NO:16);

(e) a protein whose amino acid sequence consists of at least 30 contiguous amino acids of SEQ ID NO:16;

(f) a protein whose amino acid sequence consists of at least 50 contiguous amino acids of SEQ ID NO:16; and

(g) a protein encoded by the human cDNA contained in ATCC Deposit No. 97102;

(II) an isolated antibody or fragment thereof obtained from an animal that has been immunized with a protein selected from the group consisting of:

(h) a protein whose an amino acid sequence is at least 90% to the deduced amino acid sequence as set forth in Figure 9 (SEQ ID NO:16);

(i) a protein comprising the amino acid sequence as set forth in Figure 9 (SEQ ID NO:16);

(j) a protein who amino acid sequence is at least 90% to the amino acid sequence consisting of amino acids 2 to 323 as set forth in Figure 9 (SEQ ID NO:16);

(k) a protein comprising the amino acid sequence consisting of amino acids 2 to 323 as set forth in Figure 9 (SEQ ID NO:16);

(l) a protein whose amino acid sequence consists of at least 30 contiguous amino acids of SEQ ID NO:16;

(m) a protein whose amino acid sequence consists of at least 50 contiguous amino acids of SEQ ID NO:16; and

(n) a protein encoded by the human cDNA contained in ATCC Deposit No. 97102 (claim 27),

the antibody or fragment thereof of claim 27 that specifically binds protein (a) (claim 28),

the antibody or fragment thereof of claim 27 that specifically binds protein (a) (claim 28),

the antibody or fragment thereof of claim 27 that specifically binds protein (b) (claim 29),

the antibody or fragment thereof of claim 27 that specifically binds protein (c) (claim 30),

the antibody or fragment thereof of claim 27 that specifically binds protein (d) (claim 31),

the antibody or fragment thereof of claim 27 that specifically binds protein (e) (claim 32),

the antibody or fragment thereof of claim 27 that specifically binds protein (f) (claim 33),

the antibody or fragment thereof of claim 27 that specifically binds protein (g) (claim 34),

the antibody or fragment thereof of claim 27 that specifically binds protein (h) (claim 35),

the antibody or fragment thereof of claim 27 that specifically binds protein (i) (claim 36),

the antibody or fragment thereof of claim 27 that specifically binds protein (j) (claim 37),

the antibody or fragment thereof of claim 27 that specifically binds protein (k) (claim 38),

the antibody or fragment thereof of claim 27 that specifically binds protein (l) (claim 39),

the antibody or fragment thereof of claim 27 that specifically binds protein (m) (claim 40),

the antibody or fragment thereof of claim 27 that specifically binds protein (n) (claim 41),

the antibody or fragment thereof of claim 27 wherein said antibody or fragment thereof is polyclonal (claim 45);

the antibody or fragment thereof of claim 27 which is labeled (claim 46),

the antibody or fragment thereof of claim 27 wherein said antibody or fragment thereof specifically binds to said protein in Western blot or ELISA (claim 47).

Oda et al. teaches a novel lectin protein, designated L-36, which has a 77.7% sequence identity to the polypeptide of SEQ ID NO:16 as evidenced by the attached sequence comparison.

The Board of Patent Appeals and interferences has taken the position that once an antigen has been isolated, the manufacture of antibodies against antigen, which include polyclonal antibodies, is *prima facie* obvious. See Ex parte Ehrlich, 3 USPQ 2d 1011 (PTO Bd. Pat. APP. & Int. 1987), Ex parte Sugimoto, 14 USPQ 2d 1312 (PTO Bd. Pat. App. & Int. 1990). Thus given the isolated antigen of Oda et al, it would have been prima facie obvious to make polyclonal antibodies to the prior art polypeptide and it is clear given the identity of the instantly claimed polypeptide of SEQ ID NO:16 and the polypeptide of Oda et al that a subset of the antibodies produced would be expected to bind and to the polypeptide of SEQ ID NO:16. Further, it would have been obvious to

use the antibodies in Western blot or ELISA assays to identify expression patterns of the protein of ODA and to detectably label the antibodies for this purpose.

13. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine M. Joyce whose telephone number is 571-272-3321. The examiner can normally be reached on Monday thru Friday, 10:15 - 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

Catherine Joyce
Examiner
Art Unit 1642